REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-28 are pending in the present application. Claims 1-9 and 23-25 were rejected in the outstanding Official Action. Claims 10-22 were withdrawn.

In the present amendment, claims 1-9 and 23-25 have been amended to address several informalities found within the claims. In addition, claims 26-28 have been added to vary the scope of the claimed subject matter. Support for claims 26-28 may be found in claims 1, 8 and 23.

In the outstanding Official Action, claims 1-7, 9 and 23-24 were rejected under 35 USC §103(a) as allegedly being unpatentable over STACK in view of SUZUKI et al. and further in view of MEIER et al. This rejection is respectfully traversed.

In imposing the rejection, the Official Action states that the rejection is based on the "well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. *In re Sussman,* 1943 C.D. 518. Applicants assume that the above-identified citation is directed to *In re Sussman,* 30 CCPA 1107, 136 F.2d 715, 58 USPQ 262 (1943), a case decided prior to the 1952 patent act. If this is not the case, applicants

respectfully request that the Examiner provides a full citation to the above-identified case in the next response from the Patent Office.

In any event, upon reviewing STACK, SUZUKI et al. and MEIER et al., applicants believe that the proposed combination of references does not render obvious the claimed invention nor satisfy the requirements of the above-identified case law.

While the Official Action contends that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, applicants note that the teachings of STACK, SUZUKI et al. and MEIER et al. do not teach that each ingredient would have an additive effect or be used for the same purpose. STACK and SUZUKI et al. are directed to antidepressants. MEIER et al. teach that *Vitex agnus-castus* may be used in the treatment of premenstrual symptoms.

Thus, the compositions taught by STACK, SUZUKI et al. and MEIER et al. are not used for the same purpose.

In addition, the Examiner's attention is respectfully directed to the declaration by Eline M. van der Beek. It is believed that the declaration provides unexpected evidence of the advantageous effects of the combination of cocoa and a plant-derived dopamine D2 receptor agonist.

Thus, applicants believe that it cannot be said that the combining of the claimed components does not produced unexpected results.

At this time, the Examiner is respectfully reminded that a critical step in analyzing obviousness pursuant to 35 U.S.C. §103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, only guided by the publications and then-accepted wisdom in the field. Close adherence to this methodology is important in cases where the invention itself may prompt an Examiner to "fall victim to the insidious effect of a hindsight syndrome, wherein that which only the invention taught is used against its teacher." Indeed, to establish a prima facie case of obviousness, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab,* 217 F.3d 1365, 1369-70, 55 USPQ 2d 1313, 1362 (Fed. Circ. 2000).

The fact that the prior art could be so modified would not have made the modification itself obvious unless the cited publications themselves suggested the desirability of the modification. *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Circ. 1984).

Upon reviewing the cited publications, applicants believe that none of the publications themselves disclose or

suggest combining and modifying the respective teachings in a manner so as to obtain the claimed invention.

STACK describes psychotropic piperinidinylmethyl benzodioxanes. The described compounds are chemically synthesized (column 4, line 26 - column 5, line 26). Applicants' invention relates to plant-derived dopamine D2 receptor agonists, particularly labdane diterpoenoid. In addition, STACK does not describe nor provide any hint towards the problems related to the administration of cocoa. STACK simply fails to suggest that cocoa can be advantageously combined with a dopamine D2 receptor agonist. As a result, applicants believe that STACK stands in contrast to the claimed invention.

In an effort to remedy the deficiencies of STACK, the Official Action cites to SUZUKI et al. SUZUKI et al. relate to chemically synthesized xanthines derivative or pharmaceutically acceptable salt thereof. Formula (I) (column 2) provides the chemical structure of the xanthine derivatives to which it relates. As described in column 2, lines 16-40, R4 represents cycloalkyl, --(CH2)n --R5 (in which R5 represents substitute or unsubstituted aryl or a substituted or unsubstituted heterocyclic group; and n is an integer of 0 to 4), or a structure as depicted in column 2, lines 20-25, (in which Y1 and Y2 represent independently hydrogen, jalopgen, or lower alkyl; and Z represents substituted or unsubstituted aryl, the structure as depicted in column 2, lines 30-35 (in which R6 represents

hydrogen, hydroxyl, lower alkyl, lower alkoxy, halogen, nitro, or amino; and m represents an integer of 1 to 3), or a substitute or unsubstituted heterocyclic group). The cocoa xanthines do not overlap with this structure. The main cocoa xanthines (i.e. caffeine and theobromine) have hydrogen on the R4 position of formula (I) as depicted by SUZUKI et al. in column 2. Thus, SUZUKI et al. relate to different molecule and does not relate to cocoa xanthines or cocoa powder. As a result, it is believed that SUZUKI et al. fail to remedy the deficiencies of STACK.

In an effort to remedy the deficiencies of STACK and SUZUKI et al., the Official Action cites to MEIER et al.

MEIER et al. relate to the pharmacological effects of ethanolic *Vitex agnus-castus* fruit extract. The MEIER et al. publication is specifically concerned with premenstrual syndrome. According to MEIER et al., the results indicate a dopaminergic effect of *Vitex agnus-castus* extracts and suggests additional pharmacological actions via opoid receptors.

MEIER et al. do not relate to the problems associated with the administration of cocoa, nor does MEIER et al. give nay hint towards the advantageous combination of cocoa and a dopamine D2 receptor agonist. In fact, MEIER et al. do not even use the word cocoa. Thus, it is believe that MEIER et al. fail to remedy the deficiencies of STACK and SUZUKI et al.

Moreover, the three references cited by the Official Action do not in any way refer to the others; no explicit or

implicit suggestion or motivation in these references is present that would have motivated the skilled man to combine the above cited references and to select the components cited in the references for combining them to applicants' disclosure.

In reviewing the cited publication, the cited references fail to provide any teaching, alone or in combination, that would have suggested the combination of cocoa and a plant-derived dopamine D2 receptor agonist. Indeed, not one of the references relates to cocoa, or even mentions cocoa. Furthermore, not one of the documents suggest or gives any hint towards the advantageous use of a dopamine D2 receptor agonist to reduce the side effects of cocoa.

As a result, applicants believe that the proposed combination of references fails to disclose or suggest the claimed invention.

Applicants also traverse the assertion that one of ordinary skill in the art would have been motivated to modify the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. It is believed that none of the publications disclose or suggest optimizing the claimed components in a manner so as to obtain the claimed invention. Indeed, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the

determination of the parameter or the variable might be characterized as routine or obvious. *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Thus, as none of the publications teach that the combination and proportions are result-effective variables, applicants believe that one of ordinary skill in the art would lack the motivation to optimize the parameters as suggested by the Official Action.

Claims 1-8 and 23-25 were rejected under 35 USC §103(a)) as allegedly being unpatentable over SUZUKI et al. in view of FOSTER et al. This rejection is respectfully traversed.

In imposing the rejection, the Official Action also acknowledges that the rejection is based on *In re Sussman*, 1943 C.D. 518. As noted above, SUZUKI et al. is directed to antidepressants. FOSTER et al. teach that the genus *Cimicifuga racemosa* may be used for in treating premenstrual symptoms.

While the Official Action notes that FOSTER et al. discuss the treatment of "depressive moods", applicants note that these "depressive moods" are specifically linked to premenopausal and menopausal symptoms and are not related to clinical depression.

Indeed, the Examiner is respectfully reminded that a prior art must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721

F.2d 1540, 220 USPQ 303 (Fed. Circ. 1983), cert. denied, 469 USPQ 851 (1984).

Thus, applicants believed that it cannot be said that the proposed combination of SUZUKI et al. and FOSTER et al. teach that the components are administered for the same purpose.

As noted above, applicants also submit herewith a declaration by Eline M. van der Beek that provides unexpected evidence of the advantageous effects of a combination of cocoa and a plant-derived dopamine D2 receptor agonist.

Thus, in view of the teachings of SUZUKI et al. in view of FOSTER et al. and the declaration, applicants believe that the proposed combination of references fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action.

Please charge the fee of $200 for the extra independent claim and $150 for the three claims of any type added herewith, to Deposit Account No. 25-0120.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

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The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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Appendix:

The Appendix includes the following item:

- declaration by Eline M. van der Beek